

## **REMARKS**

Claims 1-6 were pending in the application and were rejected. Claims 1-6 are herein amended.

### **Preliminary Comments**

The Amendment filed on December 19, 2007 included a Declaration by the inventor. The experimental data referred to in the Declaration was inadvertently omitted. Thus, attached hereto is a re-submission of the Amendment and Declaration, with the experimental data included.

### **Article 19 Amendments**

From the statement in the last paragraph of page 3 of the Office Action "...the limitation 'for a non-viral gene delivery sector' is functional language ...", it appears that the U.S.P.T.O. is not examining the claims as amended in the Article 19 Amendments. The U.S.P.T.O. electronic file wrapper has an entry labeled "claims" which contains the original claims and the Article 19 amended claims.

In view of the above, Applicant respectfully requests that the U.S.P.T.O. consider the Article 19 amended claims. For clarity, Applicant herewith submits a clean copy of the claims including the Article 19 amendments.

### **Objections to the Claims**

**Claims 1-4 are objected to as allegedly containing "informalities."**

The Office Action states that in the description of R<sub>7</sub> semicolons are used to separate the members of the group rather than commas. In response, Applicant herein amends claims 1-4 to correct for this and other informalities. Favorable reconsideration is respectfully

requested.

**Applicant's Response to Claim Rejections under 35 U.S.C. §102**

**Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Onishi (US Pat. 4,816,540).**

It is the position of the Office Action that that Onishi discloses Applicant's claimed copolymers and that the functional language "for a non-viral gene delivery sector" does not materially change the structure of the polymer.

The Office Action considers the cationic graft-copolymers of Onishi to fully encompass Applicant's claims 1 and 2. That is, the Office Action's position is that the cationic graft-copolymers of Onishi meet the recited cationic graft-copolymers and that such cationic graft-copolymers also inherently would be capable of the claimed function of being a non-viral gene delivery vector.

In response, Applicant herein amends claims 1 and 2 in order to recite "a non-viral gene delivery vector formed of an aqueous solution of a cationic graft-copolymer..." Onishi does not disclose or suggest such an aqueous solution. Favorable reconsideration is respectfully requested.

**Applicant's Response to Claim Rejections under 35 U.S.C. §103**

**Claims 3-6 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Onishi (US Pat. 4,816,540) in view of Pack, Gene-Delivery Polymers.**

It is the position of the Office Action that Onishi discloses the invention as claimed, wit the exception of teaching forming a complex with DNA. The Office Action cites Pack

as teaching forming a complex between a cationic graft polymer and DNA (Section 2.2.2).

Onishi claims a cationic graft-copolymer, useful as a micro carrier for cell cultivation, comprising a unit derived from a cationic polysaccharide whereas the present invention claims a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups comprising a unit derived from a cationic a water-soluble linear polysaccharide. Although both the inventions are directed at a cationic graft-copolymer, Onishi does not disclose or teach or suggest any possibility for a non-viral gene delivery vector by the graft copolymer. Also, a person having ordinary skill in the art would not have been prompted to make use of a cationic water-soluble linear polysaccharide in the preparation of cationic graft-copolymer.

Though the Office Action cites Pack (Gene-delivery polymers) as teaching forming a complex between a cationic graft polymer and DNA (Section 2.2.2), Pack also shows that the polymers are not copolymers, but rather homopolymers by the characterization that the polymers themselves comprise linear, branched, and dendrimeric structures. On the other hand, a cationic graft-copolymer of this invention is characterized as copolymer having a hydrophilic-hydrophobic micro-separated-domain as shown in the specification.

In section 2.2 Pack also shows various synthetic vector, including DEAE-dextran of a starting material for this invention, has suffered from problems including toxicity, low gene transfer efficiency, and *in vivo* instability.

It would not have been obvious that a cationic graft-copolymer obtained by graft-polymerizing methyl methacrylate of an olefin monomer onto DEAE-dextran of a cationic derivative of a water-soluble linear polymer having hydroxyl groups can solve these problems, especially of toxicity and low gene transfer efficiency. Samples 1 having a 150%

weight increase, 2 having a 200% weight increase and 3 having a 300% weight increase were prepared following procedure of Example 1.

With the transfection efficiency, transfection activity was determined using the X-gal staining ( $\beta$ -galactosidase activities in tissue) method and a value 3 times higher was confirmed for sample 1 and sample 2 than for the starting DEAE-dextran hydrochloride.

Formation of a complex between nucleic acids (DNA or RNA) and cationic graft-copolymers, such as DEAE-dextran-MMA copolymer, is improved as compared with DEAE-dextran of the starting material.

In these Examples, a complex of sample 1 between DNA and DEAE-dextran-MMA-Copolymer hydrochloride having a 150% weight increase was formed in 2 hours. A complex of sample 2 and sample 3 between DNA and DEAE-Dextran-MMA-copolymer hydrochloride having a 200% and 300% weight increase were formed in 1 hour and 0.5 hours, respectively. However, a complex between DNA and DEAE-dextran hydrochloride was formed in 96 hours.

Additionally, Applicant herewith submits experimental data which shows that the efficacy/transfection efficiency of the claimed non-viral gene delivery vector comprising of the graft copolymer compared with a prior known vector. Accordingly, Applicant respectfully submits that the attached data is sufficient to prove the higher efficacy/efficiency of a transfection with the graft copolymer by comparison of a starting material.

Specifically, Applicant submits the data of Example 1(DDMC) compared to PolyFect Reagent (QIAGEN GmbH) having dendrimeric structures shown in Section 2.2.2 of Pack (Gene-delivery polymers). The data is for the transfection for COS7 cells by

pGL3DNA/DDMC. The cells were ready to harvest 72 hours after transfection, and were assayed for luciferase activity.

Accordingly, in view of the above remarks and the cited art, Applicant respectfully submits that the claimed gene delivery of polymers would not have been obvious to one having ordinary skill in the art. Favorable reconsideration is respectfully requested.

### **Applicant's Response to Double Patenting Rejections**

**Claims 1 and 2 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent No. 4,816,540.**

**Claims 3-6 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent No. 4,816,540 in view of Pack, Gene-Delivery Polymers.**

In response, Applicant respectfully submits that since the §102 and §103 rejections are overcome on the technical merits, the obviousness-type double patenting rejections are also overcome. Favorable reconsideration is respectfully requested.

### **Conclusion**

In view of the aforementioned amendments and accompanying remarks, Applicant submits that the claims, as herein amended, are in condition for allowance. Applicant requests such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicant's undersigned attorney to arrange for an

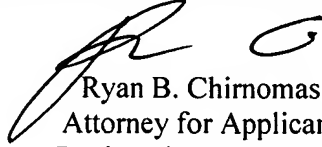
Amendment Under 37 C.F.R. §1.111  
Application No. 10/536,901  
Attorney Docket No. 052603

interview to expedite the disposition of this case.

If this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

**WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP**



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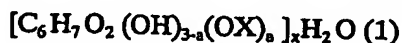
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Enclosure: Clean copy of Article 19 Amendments corresponding to claims 1-4  
Declaration under 37 CFR 1.132 (including experimental data)

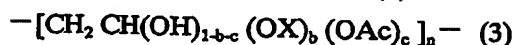
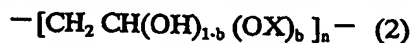
## CLAIMS

What is claimed is:

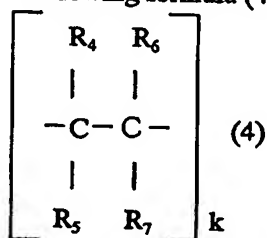
1. A cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups, for a non-viral gene delivery vector, comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



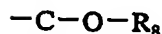
Wherein X is a  $-(CH_2)_mR_1$  organic radical where  $R_1$  is a member of the class consisting of  $-NH_2$  radical,  $-N(CH_3)_2$  radical,  $-N(C_2H_5)_2$  radical,  $-N^+(C_2H_5)_3$  radical,  $-N^+(CH_2)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$  radical,  $-C_6H_4NH_2$  radical, and  $-COC_6H_4NH_2$  radical,  $-COR_2$  radical where  $R_2$  is  $-CH_2NH_2$  or  $-C_6H_4NH_2$ ,  $-CH_2CH(OH)CH_2R_3$  radical where  $R_3$  is  $-NH_2$ ,  $-N(CH_3)_2$ ,  $-N(C_2H_5)_2$ , and  $-N^+(C_2H_5)_3$  radical, m is a natural number of 1 to 3, a is a positive number having a value of  $0 < a < 3$ , b is a positive number having a value of  $0 < b < 1$ , x and n are natural numbers having a value of 5 or more,  $1 > b + c$ , and Ac is acetyl radical; and a unit derived from a polymerize-able olefin compound of the following formula (4)



Wherein  $R_4$ ,  $R_5$  and  $R_6$  are each selected from the group consisting of hydrogen and  $CH_3$  and  $R_7$  is a member of the group consisting of

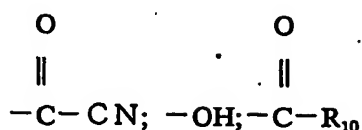
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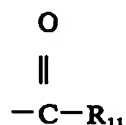


Where  $R_8$  is a member of the class consisting of hydrogen,  $C_1 - C_{12}$  alkyl radicals, cyclohexyl radical,  $C_1 - C_4$  hydroxyalkyl radicals,  $C_1 - C_8$  aminoalkyl radicals,  $C_1 - C_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $C_1 - C_4$  lower alkyl-substituted tetrahydrofuran radical, benzyl radical, the  $(CH_2CH_2O)_y$   $CH_2CH_2OH$  radical where y is a positive integer from 1 to 10, and  $-N(R_9)_2$  where the two  $R_9$ 's which may be the same or different, are

either hydrogen or a C<sub>1</sub>–C<sub>4</sub> alkyl radical;

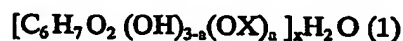


Where R<sub>10</sub> is a C<sub>1</sub>–C<sub>8</sub> alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

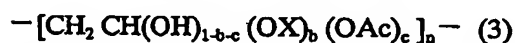
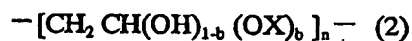


Where R<sub>11</sub> is NH<sub>2</sub>, NHCH<sub>3</sub>, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical.

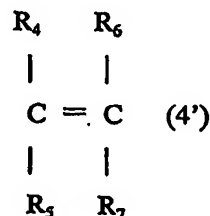
2. A process for preparing a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups, for a non-viral gene delivery vector, which comprises reacting a cationic water-soluble linear polysaccharide of the following formula (1)



or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)

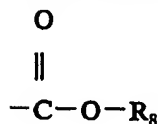


Wherein X is a  $-(\text{CH}_2)_m\text{R}_1$  organic radical where R<sub>1</sub> is a member of the class consisting of  $-\text{NH}_2$  radical,  $-\text{N}(\text{CH}_3)_2$  radical,  $-\text{N}(\text{C}_2\text{H}_5)_2$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical,  $-\text{N}^+(\text{CH}_2)_2\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_2\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_2(\text{C}_2\text{H}_5)\text{N}(\text{C}_2\text{H}_5)_2$  radical,  $-\text{C}_6\text{H}_4\text{NH}_2$  radical, and  $-\text{COC}_6\text{H}_4\text{NH}_2$  radical,  $-\text{COR}_2$  radical where R<sub>2</sub> is  $-\text{CH}_2\text{NH}_2$  or  $-\text{C}_6\text{H}_4\text{NH}_2$ ,  $-\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{R}_3$  radical where R<sub>3</sub> is  $-\text{NH}_2$ ,  $-\text{N}(\text{CH}_3)_2$ ,  $-\text{N}(\text{C}_2\text{H}_5)_2$ , and  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical, m is a natural number of 1 to 3, a is a positive number having a value of  $0 < a < 3$ , b is a positive number having a value of  $0 < b < 1$ , x and n are natural numbers having a value of 5 or more,  $1 > b + c$ , and Ac is acetyl radical; with a polymerize-able olefin compound of the formula (4')

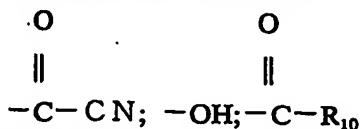


Wherein R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> are each selected from the group consisting of hydrogen and CH<sub>3</sub>

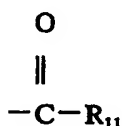
and  $R_7$  is a member of the group consisting of



Where  $R_8$  is a member of the class consisting of hydrogen,  $C_1 - C_{12}$  alkyl radicals, cyclohexyl radical,  $C_1 - C_4$  hydroxyalkyl radicals,  $C_1 - C_8$  aminoalkyl radicals,  $C_1 - C_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $C_1 - C_4$  lower alkyl -substituted tetrahydrofuran radical, benzyl radical, the  $(\text{CH}_2\text{CH}_2 \text{O})_y \text{CH}_2\text{CH}_2\text{OH}$  radical where  $y$  is a positive integer from 1 to 10, and  $-\text{N}(\text{R}_9)_2$  where the two  $\text{R}_9$ s which may be the same or different, are either hydrogen or a  $C_1 - C_4$  alkyl radical;

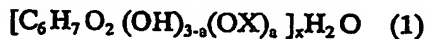


Where  $\text{R}_{10}$  is a  $C_1 - C_8$  alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

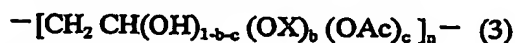
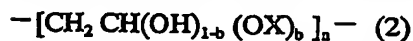


Where  $\text{R}_{11}$  is  $\text{NH}_2$ ,  $\text{NHCH}_3$ ,  $\text{N,N}$ -dimethylamino radical,  $\text{N,N}$ -dimethylaminopropylamino radical, and morpholine radical.

3. A complex between a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups and DNA, comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



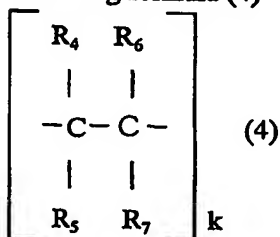
or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



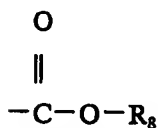
Wherein  $\text{X}$  is a  $-(\text{CH}_2)_m \text{R}_1$  organic radical where  $\text{R}_1$  is a member of the class consisting of

$-\text{NH}_3^+$  radical,  $-\text{NH}^+(\text{CH}_3)_2$  radical,  $-\text{NH}^+(\text{C}_2\text{H}_5)_2$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical,  $-\text{N}^+(\text{CH}_2)_2\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_2\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_2(\text{C}_2\text{H}_5)\text{N}(\text{C}_2\text{H}_5)_2$  radical,  $-\text{C}_6\text{H}_4\text{NH}_3^+$  radical, and  $-\text{COC}_6\text{H}_4\text{NH}_3^+$  radical,  $-\text{COR}_2$  radical where  $\text{R}_2$  is  $-\text{CH}_2\text{NH}_3^+$  or  $-\text{C}_6\text{H}_4\text{NH}_3^+$ ,  $-\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{R}_3$  radical

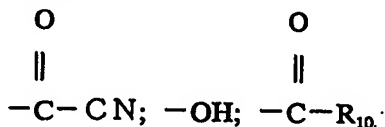
where  $R_3$  is  $-\text{NH}_3^+$ ,  $-\text{NH}^+(\text{CH}_3)_2$ ,  $-\text{NH}^+(\text{C}_2\text{H}_5)_2$  and  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical,  $m$  is a natural number of 1 to 3,  $a$  is a positive number having a value of  $0 < a < 3$ ,  $b$  is a positive number having a value of  $0 < b < 1$ ,  $x$  and  $n$  are natural numbers having a value of 5 or more,  $1 > b + c$ , and  $\text{Ac}$  is acetyl radical; a unit derived from a polymerize-able olefin compound of the following formula (4)



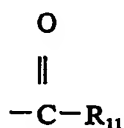
Wherein  $R_4$ ,  $R_5$  and  $R_6$  are each selected from the group consisting of hydrogen and  $\text{CH}_3$  and  $R_7$  is a member of the group consisting of



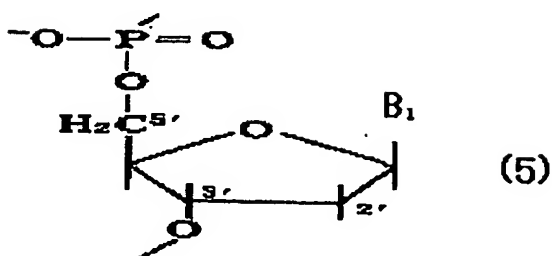
Where  $R_8$  is a member of the class consisting of hydrogen,  $\text{C}_1 - \text{C}_{12}$  alkyl radicals, cyclohexyl radical,  $\text{C}_1 - \text{C}_4$  hydroxyalkyl radicals,  $\text{C}_1 - \text{C}_8$  aminoalkyl radicals,  $\text{C}_1 - \text{C}_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $\text{C}_1 - \text{C}_4$  lower alkyl -substituted tetrahydrofuran radical, benzyl radical, the  $(\text{CH}_2\text{CH}_2\text{O})_y$ ,  $\text{CH}_2\text{CH}_2\text{OH}$  radical where  $y$  is a positive integer from 1 to 10, and  $-\text{N}(\text{R}_9)_2$  where the two  $\text{R}_9$ s which may be the same or different, are either hydrogen or a  $\text{C}_1 - \text{C}_4$  alkyl radical;



Where  $\text{R}_{10}$  is a  $\text{C}_1 - \text{C}_8$  alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

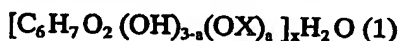


Where  $\text{R}_{11}$  is  $\text{NH}_2$ ,  $\text{NHCH}_3$ ,  $\text{N,N}$ -dimethylamino radical,  $\text{N,N}$ -dimethylaminopropylamino radical, and morpholine radical; and a unit derived from a poly(deoxyribonucleotide) of the following formula (5) as a recurring unit.

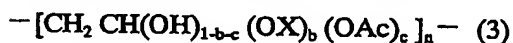
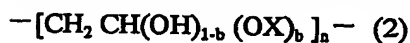


Where  $B_1$  is a base selected from the group of adenine, thymine, guanine, and cytosine.

4. A complex between a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups and RNA, comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



Wherein X is a  $-(CH_2)_m R_1$  organic radical where  $R_1$  is a member of the class consisting of

$-NH_3^+$  radical,  $-NH^+(CH_3)_2$  radical,  $-NH^+(C_2H_5)_2$  radical,  $-N^+(C_2H_5)_3$  radical,

$-N^+(CH_2)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2CH_2CH(OH)CH_3$  radical,

$-N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$  radical,  $-C_6H_4NH_3^+$  radical, and  $-COC_6H_4NH_3^+$  radical,

$-COR_2$  radical where  $R_2$  is  $-CH_2NH_3^+$  or  $-C_6H_4NH_3^+$ ,  $-CH_2CH(OH)CH_2 R_3$  radical

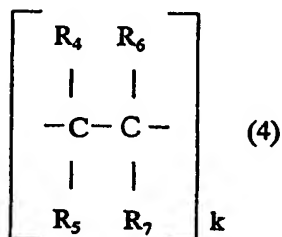
where  $R_3$  is  $-NH_3^+$ ,  $-NH^+(CH_3)_2$ ,  $-NH^+(C_2H_5)_2$ , and  $-N^+(C_2H_5)_3$  radical, m is a natural

number of 1 to 3, a is a positive number having a value of  $0 < a < 3$ , b is a positive number

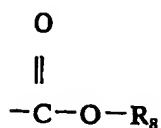
having a value of  $0 < b < 1$ , x and n are natural numbers having a value of 5 or more,  $1 > b + c$ ,

and Ac is acetyl radical; a unit derived from a polymerize-able olefin compound of the

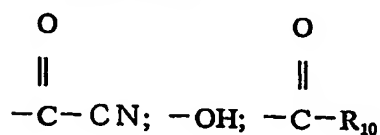
following formula (4)



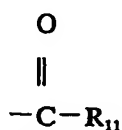
Wherein  $R_4$ ,  $R_5$  and  $R_6$  are each selected from the group consisting of hydrogen and  $CH_3$  and  $R_7$  is a member of the group consisting of



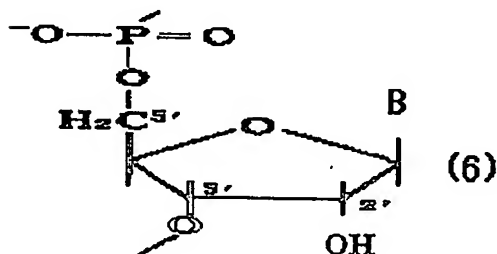
Where  $\text{R}_8$  is a member of the class consisting of hydrogen,  $\text{C}_1 - \text{C}_{12}$  alkyl radicals, cyclohexyl radical,  $\text{C}_1 - \text{C}_4$  hydroxyalkyl radicals,  $\text{C}_1 - \text{C}_8$  aminoalkyl radicals,  $\text{C}_1 - \text{C}_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $\text{C}_1 - \text{C}_4$  lower alkyl -substituted tetrahydrofuran radical, benzyl radical, the  $(\text{CH}_2\text{CH}_2\text{O})_y\text{CH}_2\text{CH}_2\text{OH}$  radical where  $y$  is a positive integer from 1 to 10, and  $-\text{N}(\text{R}_9)_2$  where the two  $\text{R}_9$ 's which may be the same or different, are either hydrogen or a  $\text{C}_1 - \text{C}_4$  alkyl radical;



Where  $\text{R}_{10}$  is a  $\text{C}_1 - \text{C}_8$  alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where  $\text{R}_{11}$  is  $\text{NH}_2$ ,  $\text{NHCH}_3$ ,  $\text{N,N}$ -dimethylamino radical,  $\text{N,N}$ -dimethylaminopropylamino radical, and morpholine radical; and a unit derived from a poly(ribonucleotide) of the following formula(6) as a recurring unit.



Where B is a base selected from the group of adenine, uracil, guanine, and cytosine.

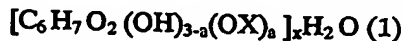
5. A gene delivery system using a complex between the cationic graft-copolymer and DNA, of Claim 3.
6. A gene delivery system using a complex between the cationic graft-copolymer and RNA, of Claim 4.

## AMENDED CLAIMS

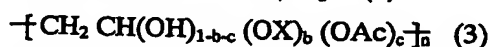
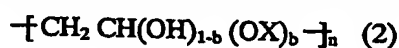
[Received by the International Bureau on 01 October 2004 (01.10.04):  
original claims 1-4 are amended and all other claims are retained unchanged. (6 pages)]

What is claimed is:

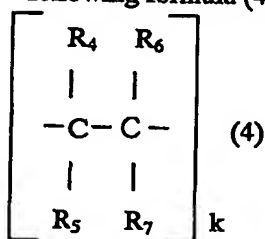
1. (amended) A non-viral gene delivery vector formed from a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



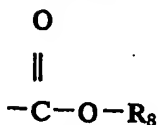
or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



Wherein X is a  $-(CH_2)_m R_1$  organic radical where  $R_1$  is a member of the class consisting of  $-NH_2$  radical,  $-N(CH_3)_2$  radical,  $-N(C_2H_5)_2$  radical,  $-N^+(C_2H_5)_3$  radical,  $-N^+(CH_2)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$  radical,  $-C_6H_4NH_2$  radical, and  $-COC_6H_4NH_2$  radical,  $-COR_2$  radical where  $R_2$  is  $-CH_2NH_2$  or  $-C_6H_4NH_2$ ,  $-CH_2CH(OH)CH_2R_3$  radical where  $R_3$  is  $-NH_2$ ,  $-N(CH_3)_2$ ,  $-N(C_2H_5)_2$ , and  $-N^+(C_2H_5)_3$  radical,  $m$  is a natural number of 1 to 3,  $a$  is a positive number having a value of  $0 < a < 3$ ,  $b$  is a positive number having a value of  $0 < b < 1$ ,  $x$  and  $n$  are natural numbers having a value of 5 or more,  $1 > b + c$ , and  $Ac$  is acetyl radical; and a unit derived from a polymerize-able olefin compound of the following formula (4)

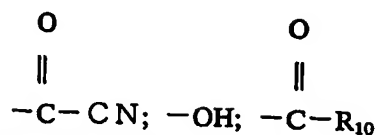


Wherein  $R_4$ ,  $R_5$  and  $R_6$  are each selected from the group consisting of hydrogen and  $CH_3$  and  $R_7$  is a member of the group consisting of

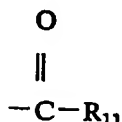


Where  $R_8$  is a member of the class consisting of hydrogen,  $C_1-C_{12}$  alkyl radicals, cyclohexyl radical,  $C_1-C_4$  hydroxyalkyl radicals,  $C_1-C_8$  aminoalkyl radicals,  $C_1-C_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $C_1-C_4$  lower alkyl-substituted tetrahydrofuran radical, benzyl radical, the  $(CH_2CH_2O)_yCH_2CH_2OH$  radical where  $y$  is a positive integer from 1 to 10, and  $-N(R_9)_2$  where the two  $R_9$ s which may be the same or different, are

either hydrogen or a C<sub>1</sub>–C<sub>4</sub> alkyl radical;

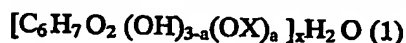


Where R<sub>10</sub> is a C<sub>1</sub>–C<sub>8</sub> alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

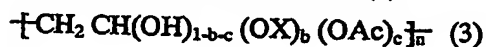
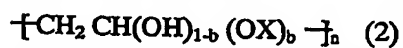


Where R<sub>11</sub> is NH<sub>2</sub>, NHCH<sub>3</sub>, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical.

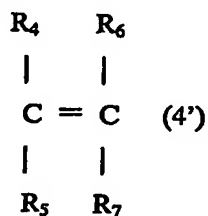
2. (amended) A process for preparing a non-viral gene delivery vector formed from a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups which comprises reacting a cationic water-soluble linear polysaccharide of the following formula (1)



or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)

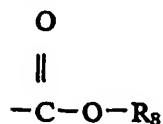


Wherein X is a  $-(\text{CH}_2)_m\text{R}_1$  organic radical where R<sub>1</sub> is a member of the class consisting of  $-\text{NH}_2$  radical,  $-\text{N}(\text{CH}_3)_2$  radical,  $-\text{N}(\text{C}_2\text{H}_5)_2$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical,  $-\text{N}^+(\text{CH}_2)_2\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_2\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$  radical,  $-\text{N}^+(\text{C}_2\text{H}_5)_2(\text{C}_2\text{H}_5)\text{N}(\text{C}_2\text{H}_5)_2$  radical,  $-\text{C}_6\text{H}_4\text{NH}_2$  radical, and  $-\text{COC}_6\text{H}_4\text{NH}_2$  radical,  $-\text{COR}_2$  radical where R<sub>2</sub> is  $-\text{CH}_2\text{NH}_2$  or  $-\text{C}_6\text{H}_4\text{NH}_2$ ,  $-\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{R}_3$  radical where R<sub>3</sub> is  $-\text{NH}_2$ ,  $-\text{N}(\text{CH}_3)_2$ ,  $-\text{N}(\text{C}_2\text{H}_5)_2$ , and  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical, m is a natural number of 1 to 3, a is a positive number having a value of  $0 < a < 3$ , b is a positive number having a value of  $0 < b < 1$ , x and n are natural numbers having a value of 5 or more,  $1 > b + c$ , and Ac is acetyl radical; with a polymerize-able olefin compound of the formula (4')

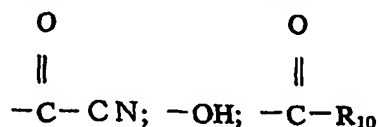


Wherein R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> are each selected from the group consisting of hydrogen and CH<sub>3</sub>

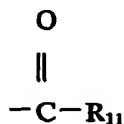
and R<sub>7</sub> is a member of the group consisting of



Where R<sub>8</sub> is a member of the class consisting of hydrogen, C<sub>1</sub>–C<sub>12</sub> alkyl radicals, cyclohexyl radical, C<sub>1</sub>–C<sub>4</sub> hydroxyalkyl radicals, C<sub>1</sub>–C<sub>8</sub> aminoalkyl radicals, C<sub>1</sub>–C<sub>8</sub> dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical, C<sub>1</sub>–C<sub>4</sub> lower alkyl-substituted tetrahydrofuran radical, benzyl radical, the (CH<sub>2</sub>CH<sub>2</sub>O)<sub>y</sub>CH<sub>2</sub>CH<sub>2</sub>OH radical where y is a positive integer from 1 to 10, and –N(R<sub>9</sub>)<sub>2</sub> where the two R<sub>9</sub>s which may be the same or different, are either hydrogen or a C<sub>1</sub>–C<sub>4</sub> alkyl radical;

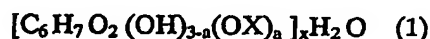


Where R<sub>10</sub> is a C<sub>1</sub>–C<sub>8</sub> alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

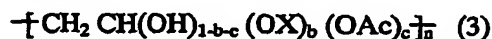
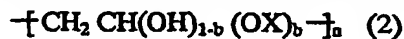


Where R<sub>11</sub> is NH<sub>2</sub>, NHCH<sub>3</sub>, N,N-dimethylamino radical, N,N-dimethylaminopropylamino radical, and morpholine radical.

3. (amended) A non-viral gene delivery vector, as the first step of transfection, using a complex between a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups and DNA, comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



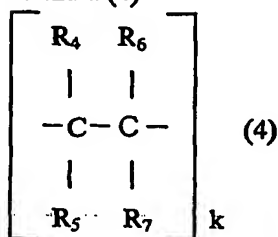
or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



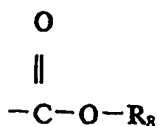
Wherein X is a –(CH<sub>2</sub>)<sub>m</sub>R<sub>1</sub> organic radical where R<sub>1</sub> is a member of the class consisting of –NH<sub>3</sub><sup>+</sup> radical, –NH<sup>+</sup>(CH<sub>3</sub>)<sub>2</sub> radical, –NH<sup>+</sup>(C<sub>2</sub>H<sub>5</sub>)<sub>2</sub> radical, –N<sup>+</sup>(C<sub>2</sub>H<sub>5</sub>)<sub>3</sub> radical, –N<sup>+</sup>(CH<sub>2</sub>)<sub>2</sub>CH<sub>2</sub>CH(OH)CH<sub>3</sub> radical, –N<sup>+</sup>(C<sub>2</sub>H<sub>5</sub>)<sub>2</sub>CH<sub>2</sub>CH(OH)CH<sub>3</sub> radical, –N<sup>+</sup>(C<sub>2</sub>H<sub>5</sub>)<sub>2</sub>(C<sub>2</sub>H<sub>5</sub>)N(C<sub>2</sub>H<sub>5</sub>)<sub>2</sub> radical, –C<sub>6</sub>H<sub>4</sub>NH<sub>3</sub><sup>+</sup> radical, and –COC<sub>6</sub>H<sub>4</sub>NH<sub>3</sub><sup>+</sup> radical,

$-\text{COR}_2$  radical where  $\text{R}_2$  is  $-\text{CH}_2\text{NH}_3^+$  or  $-\text{C}_6\text{H}_4\text{NH}_3^+$ ,  $-\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{R}_3$  radical where  $\text{R}_3$  is  $-\text{NH}_3^+$ ,  $-\text{NH}^+(\text{CH}_3)_2$ ,  $-\text{NH}^+(\text{C}_2\text{H}_5)_2$ , and  $-\text{N}^+(\text{C}_2\text{H}_5)_3$  radical,  $m$  is a natural number of 1 to 3,  $a$  is a positive number having a value of  $0 < a < 3$ ,  $b$  is a positive number having a value of  $0 < b < 1$ ,  $x$  and  $n$  are natural numbers having a value of 5 or more,  $1 > b + c$ , and  $\text{Ac}$  is acetyl radical; a unit derived from a polymerize-able olefin compound of the following

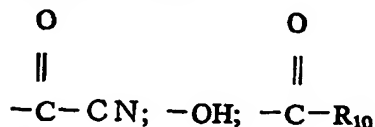
formula (4)



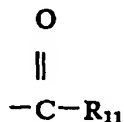
Wherein  $\text{R}_4$ ,  $\text{R}_5$  and  $\text{R}_6$  are each selected from the group consisting of hydrogen and  $\text{CH}_3$  and  $\text{R}_7$  is a member of the group consisting of



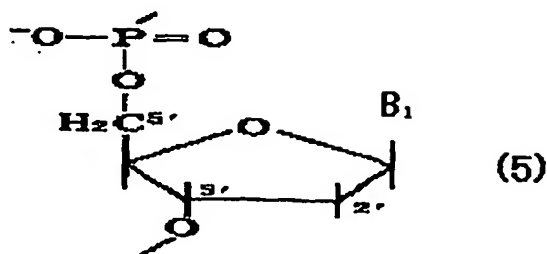
Where  $\text{R}_8$  is a member of the class consisting of hydrogen,  $\text{C}_1-\text{C}_{12}$  alkyl radicals, cyclohexyl radical,  $\text{C}_1-\text{C}_4$  hydroxyalkyl radicals,  $\text{C}_1-\text{C}_8$  aminoalkyl radicals,  $\text{C}_1-\text{C}_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $\text{C}_1-\text{C}_4$  lower alkyl-substituted tetrahydrofuran radical, benzyl radical, the  $(\text{CH}_2\text{CH}_2\text{O})_y\text{CH}_2\text{CH}_2\text{OH}$  radical where  $y$  is a positive integer from 1 to 10, and  $-\text{N}(\text{R}_9)_2$  where the two  $\text{R}_9$ s which may be the same or different, are either hydrogen or a  $\text{C}_1-\text{C}_4$  alkyl radical;



Where  $\text{R}_{10}$  is a  $\text{C}_1-\text{C}_8$  alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and

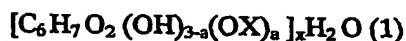


Where  $\text{R}_{11}$  is  $\text{NH}_2$ ,  $\text{NHCH}_3$ ,  $\text{N,N}$ -dimethylamino radical,  $\text{N,N}$ -dimethylaminopropylamino radical, and morpholine radical; and a unit derived from a poly(deoxyribonucleotide) of the following formula (5) as a recurring unit.

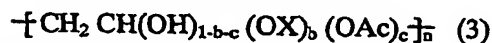
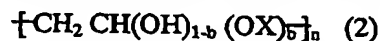


Where  $B_1$  is a base selected from the group of adenine, thymine, guanine, and cytosine.

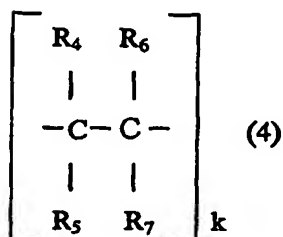
4. (amended) A non-viral gene delivery vector, as the first step of transfection, using a complex between a cationic graft-copolymer of a water-soluble linear backbone polymer having hydroxyl groups and RNA, comprising a unit derived from a cationic water-soluble linear polysaccharide of the following formula (1)



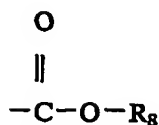
or a unit derived from a water-soluble linear polyvinylalcohol of the following formula (2) or a partial hydrolyzed alcohol of the following formula (3)



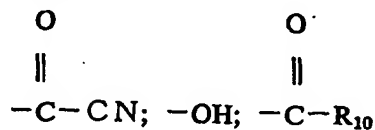
Wherein X is a  $-(CH_2)_mR_1$  organic radical where  $R_1$  is a member of the class consisting of  $-NH_3^+$  radical,  $-NH^+(CH_3)_2$  radical,  $-NH^+(C_2H_5)_2$  radical,  $-N^+(C_2H_5)_3$  radical,  $-N^+(CH_2)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2CH_2CH(OH)CH_3$  radical,  $-N^+(C_2H_5)_2(C_2H_5)N(C_2H_5)_2$  radical,  $-C_6H_4NH_3^+$  radical, and  $-COC_6H_4NH_3^+$  radical,  $-COR_2$  radical where  $R_2$  is  $-CH_2NH_3^+$  or  $-C_6H_4NH_3^+$ ,  $-CH_2CH(OH)CH_2R_3$  radical where  $R_3$  is  $-NH_3^+$ ,  $-NH^+(CH_3)_2$ ,  $-NH^+(C_2H_5)_2$ , and  $-N^+(C_2H_5)_3$  radical, m is a natural number of 1 to 3, a is a positive number having a value of  $0 < a < 3$ , b is a positive number having a value of  $0 < b < 1$ , x and n are natural numbers having a value of 5 or more,  $1 > b + c$ , and Ac is acetyl radical; a unit derived from a polymerize-able olefin compound of the following formula (4)



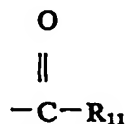
Wherein  $R_4$ ,  $R_5$  and  $R_6$  are each selected from the group consisting of hydrogen and  $CH_3$  and  $R_7$  is a member of the group consisting of



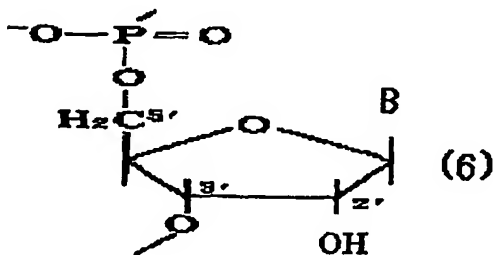
Where  $\text{R}_8$  is a member of the class consisting of hydrogen,  $\text{C}_1-\text{C}_{12}$  alkyl radicals, cyclohexyl radical,  $\text{C}_1-\text{C}_4$  hydroxyalkyl radicals,  $\text{C}_1-\text{C}_8$  aminoalkyl radicals,  $\text{C}_1-\text{C}_8$  dialkylaminoalkyl radicals, glycidyl radical, tetrahydrofuran radical,  $\text{C}_1-\text{C}_4$  lower alkyl-substituted tetrahydrofuran radical, benzyl radical, the  $(\text{CH}_2\text{CH}_2\text{O})_y\text{CH}_2\text{CH}_2\text{OH}$  radical where  $y$  is a positive integer from 1 to 10, and  $-\text{N}(\text{R}_9)_2$  where the two  $\text{R}_9$ 's which may be the same or different, are either hydrogen or a  $\text{C}_1-\text{C}_4$  alkyl radical;



Where  $\text{R}_{10}$  is a  $\text{C}_1-\text{C}_8$  alkyl radical; phenyl radical; tolyl radical; pyridine radical; pyrrolidone radical; and



Where  $\text{R}_{11}$  is  $\text{NH}_2$ ,  $\text{NHCH}_3$ ,  $\text{N,N}$ -dimethylamino radical,  $\text{N,N}$ -dimethylaminopropylamino radical, and morpholine radical; and a unit derived from a poly(ribonucleotide) of the following formula(6) as a recurring unit.



Where  $\text{B}$  is a base selected from the group of adenine, uracil, guanine, and cytosine.

**Brief Statement**

What is claimed by amendment for claim 1: Claim 1 is verified to be a non-viral gene delivery vector formed from a cationic graft-copolymer of formula(1) or formula(2) or formula(3) as detailed in application claim 1 .

What is claimed by amendment for claim 2: Claim 2 is verified to be a process for preparing a non-viral gene delivery vector formed from a cationic graft-copolymer as described in application claim 2.

What is claimed by amendment for claim 3: Claim 3 is verified to be a non-viral gene delivery vector, as the first step of transfection, using a complex between DNA and a cationic graft-copolymer as described in application claim 3.

What is claimed by amendment for claim 4: Claim 4 is verified to be a non-viral gene delivery vector, as the first step of transfection, using a complex between RNA and a cationic graft-copolymer as described in application claim 4.